

REMARKS

Claims 1, 3-5, and 179-287 were pending in this application. Applicants note with appreciation that claims 3, 181-184, 186, 187, 189-195, 198, 201, 204, 205, 207-212, 222-227, 231-245, 249-263, and 276 have been deemed allowable. Applicants also note that the restriction requirement was made final and thus, claims 4, 185, 188, 196, 197, 199, 200, 202, 203, 213-221, 228-230, 246-248, 264-275, 277 and 278, drawn to non-elected species, were withdrawn from consideration. In view of their withdrawal from consideration, claims 4, 185, 188, 196, 197, 199, 200, 202, 203, 213-221, 228-230, 246-248, 264-275, 277 and 278 have been canceled, without prejudice to Applicants' rights to pursue the subject matter of the canceled claims in related applications. Further, in order to expedite prosecution of the application, claims 190, 191, 194, 234-239, 249, 251-257, and 279 have been canceled, without prejudice to Applicants' right to pursue the subject matter of the canceled claims in related applications. Applicants have also added new claims 288-308 to more particularly point and distinctly claim the invention. Upon entry of this Amendment, claims 1, 3, 5, 179-184, 186, 187, 189, 192, 193, 195, 198, 201, 204-212, 222-227, 231-233, 240-245, 250, 258-263, 276, and 280-308 will be pending. The amendments and new claims are fully supported by the specification of the present application (see, *e.g.*, 41, line 31 to page 74, line 25, page 83, line 21 to page 88, line 7, and page 113, line 1 to page 114, line 16 of the specification), and do not constitute new matter.

Entry of the foregoing amendments and consideration of these remarks are respectfully requested.

1. THE OBJECTIONS TO CLAIMS 179 AND 279 SHOULD BE WITHDRAWN

Claims 179 and 279 are objected to because there is no reference to antibodies AFF and A13C4 in the specification of the application. Applicants note that the Examiner is correct in interpreting the reference to antibodies AFF and A13C4 as typographical errors. However, Applicants have canceled claim 279, without prejudice and have amended claim 179 so that it no longer recites the antibody AFF. Accordingly, Applicants respectfully assert that the objection to claims 179 and 279 is moot. Therefore, the objection to claims 179 and 279 cannot stand and should be withdrawn.

**2. THE DOUBLE PATENTING REJECTIONS
SHOULD BE WITHDRAWN**

**A. THE STATUTORY DOUBLE PATENTING
REJECTIONS SHOULD BE WITHDRAWN**

Claim 180 is provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 55 of copending U.S. application Serial No. 09/771,415 (the “‘415 application”). The Examiner contends that claim 180 is directed to an isolated antibody that immunospecifically binds to a RSV antigen and that claim 55 of the ‘415 application is directed to an isolated neutralizing antibody. The Examiner also contends the antibody recited in claim 180 is a neutralizing antibody based upon the specification of the present application. The Examiner, therefore, contends that the antibody recited in claim 180 of the present application is identical to the antibody recited in claim 55 of the ‘415 application. For the reasons detailed below, Applicants respectfully disagree.

An objective test for determining whether a double patenting rejection under 35 U.S.C. § 101 is appropriate is whether one of the claims in the application could be literally infringed without literally infringing the claim in the other application. *In re Vogel*, 422 F.2d 438, 441 (CCPA 1970).

Applicants respectfully assert that the same invention is not being claimed in claim 180 of the present application and claim 55 of the ‘415 application. Claim 180 does not require that the antibody be a neutralizing antibody, whereas claim 55 does. The antibody recited in claim 180 of the present application may or may not be a neutralizing antibody. The only requirement for the antibody recited in claim 180 of the present application is that the antibody immunospecifically bind to a RSV antigen. Accordingly, the antibody recited in claim 180 of the present application does not necessarily infringe the antibody recited in claim 55 of the ‘415 application. Therefore, the same invention is not being claimed in claim 180 of the present application and claim 55 of the ‘415 application, and thus, the double patenting rejection under 35 U.S.C. § 101 should be withdrawn.

Claims 1, 180, 206, 283 and 286 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1, 4, 15, 36 and 73 of copending U.S. application Serial No. 09/996,228 (the “‘228 application”). Applicants respectfully disagree.

Applicants respectfully assert that claims 1, 4, 15 and 36 of the ‘228 application were canceled, without prejudice, and that pending claim 73 of the ‘228 application is directed to a

formulation comprising palivizumab (otherwise known as “SYNAGIS®”) or a fragment thereof. Claims 1, 180, 206, 283 and 286 of the present application are not directed to palivizumab. Accordingly, the same invention is not being claimed in claims 1, 180, 206, 283 and 286 of the present application and claim 73 of the ‘228 application. Therefore, the double patenting rejection under 35 U.S.C. § 101 cannot stand and should be withdrawn.

**B. THE JUDICIALLY CREATED DOCTRINE OF
OBVIOUSNESS-TYPE DOUBLE PATENTING
REJECTIONS SHOULD BE WITHDRAWN**

Claims 1, 5, 179 and 280-287 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 55 of the ‘415 application. Although conceding that the claims are not identical, the Examiner contends that the claims are not patentably distinct from each other because the claims in the present application are drawn to antibodies that comprise SEQ ID NO:10. The Examiner contends that claim 55 of the ‘415 application is a species of claims 1, 5, and 179 of the present application. The Examiner also contends that claims 280-287 are drawn to obvious limitations of the isolated antibody of claim 55 of the ‘415 application. Applicants respectfully disagree.

Claims 1 and 5 (and claims 280-287 dependent therefrom) recite an isolated antibody comprising a variable heavy (VH) domain having a particular amino acid sequence, namely SEQ ID NO:48, and do not require that the antibody be a neutralizing antibody. Claim 55 of the ‘415 application recites a neutralizing antibody comprising a VH CDR having the same amino acid sequence as SEQ ID NO:10 in the present application. In contrast to claims 1 and 5 (and dependent claims 280-287) of the present application, claim 55 of the ‘415 application requires that the antibody be a neutralizing antibody and does not specify the two other VH CDRs that comprise the VH domain of the antibody. Production of an antibody that fulfills the criteria of claim 55 of the ‘415 application would not necessarily fall within the scope of claims 1 and 5 (and dependent claims 280-287) of the present application. Thus, Applicants respectfully assert that claims 1 and 5 (and dependent claims 280-287) are patentably distinct from claim 55 of the ‘415 application.

Claim 179 (and claims 280-287 dependent therefrom) recites an isolated antibody comprising a complementarity determining region (CDR) having a VH CDR of a particular antibody referred to in Table 2 of the specification of the application. In contrast to claim 55 of the ‘415 application, claim 179 does not require that the antibody be a neutralizing

antibody and there is no requirement that the antibody comprise a VH CDR having the amino acid sequence of SEQ ID NO:10. Accordingly, Applicants respectfully assert that claim 179 (dependent claims 280-287) is patentably distinct from claim 55 of the '415 application. Therefore, Applicants respectfully request that the rejection of claims 1, 5, 179 and 280-287 under the judicially created doctrine of obviousness-type double patenting be withdrawn.

Claims 280-282 and 284-287 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 73 of the '288 application in view of U.S. Patent No. 5,824,307 to Johnson et al. ("Johnson"). For the reasons discussed below, this rejection cannot stand and should be withdrawn.

As discussed above, pending claim 73 of the '288 application is directed to a formulation comprising palivizumab or a fragment thereof. The claims in Johnson are also directed to palivizumab. Claims 280-282 of the present application are directed to antibodies other than palivizumab. Claims 284 and 285 of the present application are directed to antibody conjugates other than palivizumab conjugates. Claim 286 and 287 of the present invention are directed to a composition and a kit, respectively, comprising antibody other than palivizumab. Accordingly, Applicants respectfully assert are claims 280-282 and 284-287 of the present application are patentably distinct from claim 73 of the '288 application in view of Johnson. Therefore, Applicants respectfully assert that the rejection of claims 280-282 and 284-287 under the judicially created doctrine of obviousness-type double patenting cannot stand and should be withdrawn.

CONCLUSION

Applicants believe that the present claims meet all the requirements for patentability. Entry of the foregoing amendments and remarks into the file of the above-identified application is respectfully requested. Withdrawal of all rejections and reconsideration of the amended claims are requested. An allowance is earnestly sought.

If any issues remain, the Examiner is requested to telephone the undersigned.

Respectfully submitted,

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